

COMMITTEE ON THE JUDICIARY

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct a hearing on "Oversight Hearing: Law Enforcement and Terrorism" on Wednesday, July 23, 2003, at 10:00 a.m. in the Hart Senate Office Building Room 216.

Agenda

The Honorable Robert S. Mueller, Director, Federal Bureau of Investigation, Department of Justice, Washington, DC; The Honorable Asa Hutchinson, Under Secretary for Border & Transportation Security, Department of Homeland Security, Washington, DC.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct an Executive Nominations hearing on Wednesday, July 23, 2003, at 2:00 p.m. in the Dirksen Senate Office Building Room 226.

Agenda

Panel I: Senators.

Panel II: Rene Alexander Acosta to be Assistant Attorney General, Civil Rights Division, United States Department of Justice and Daniel J. Bryant to be Assistant Attorney General, Office of Legal Policy, United States Department of Justice.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON ANTITRUST, COMPETITION
POLICY, AND CONSUMER RIGHTS

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights be authorized to meet to conduct a hearing on "Agriculture, Consolidation and the Smithfield/Farmland Deal" on Wednesday, July 23, 2003, at 4:00 p.m. in Room 138 of the Dirksen Senate Office Building.

Agenda

Panel I: Senator Tim Johnson.

Panel II: Mr. Joseph Sebring, CEO, John Morrell, Inc., Cincinnati, OH; Mr. William Hughes, Administrator, Division of Agricultural Development, Wisconsin Department of Agriculture, Trade and Consumer Protection, Madison, WI; Dr. Luther Tweeten, Agriculture Consultant, Columbus, OH; Mr. Russ Kremer, President, Missouri Farmers' Union, Jefferson City, MO; Mr. Patrick Bell, Farmer, Kenansville, NC; and Mr. Michael Stumo, General Counsel, Organization for Competitive Markets, Winstead, CT.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON HOUSING AND
TRANSPORTATION

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Subcommittee on Housing and Transportation of the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the

Senate on July 23, 2003, at 2:30 p.m. to conduct a hearing on "Enhancing the Role of the Private Sector in Public Transportation."

The PRESIDING OFFICER. Without objection, it is so ordered.

PRIVILEGE OF THE FLOOR

Mr. BAUCUS. Mr. President, I ask unanimous consent that Jeff Klein and Matt Linstroth of my staff be granted the privilege of the floor for the day.

The PRESIDING OFFICER. Without objection, it is so ordered.

PEDIATRIC RESEARCH EQUITY
ACT OF 2003

Mr. DEWINE. Mr. President, I ask unanimous consent the Senate proceed to the immediate consideration of calendar 183, S. 650.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 650) to amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration to require certain research into drugs used in pediatric patients.

There being no objection, the Senate proceeded to consider the bill which had been reported from the Committee on Health, Education, Labor, and Pensions, with amendments, as follows:

[Strike the part shown in black brackets and insert the part shown in italic.]

S. 650

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pediatric Research Equity Act of 2003".

SEC. 2. RESEARCH INTO PEDIATRIC USES FOR
DRUGS AND BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505A the following:

"SEC. 505B. RESEARCH INTO PEDIATRIC USES
FOR DRUGS AND BIOLOGICAL PRODUCTS.

"(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—A person that submits an application (or supplement to an application)—

"(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

"(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration;

shall submit with the application the assessments described in paragraph (2).

"(2) ASSESSMENTS.—

"(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

"(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

"(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

"(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

"(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

"(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from 1 age group can be extrapolated to another age group.

"(3) DEFERRAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

"(A) the Secretary finds that—

"(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete; or

"(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

"(iii) there is another appropriate reason for deferral; and

"(B) the applicant submits to the Secretary—

"(i) certification of the grounds for deferring the assessments; or

"(ii) a description of the planned or ongoing studies; and

"(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.

"(4) WAIVERS.—

"(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed); or

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

"(II) is not likely to be used in a substantial number of pediatric patients.

"(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group; or

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric

formulation necessary for that age group have failed.

“(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

“(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

“(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

“(1) IN GENERAL.—After providing notice in the form of a letter and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) if the Secretary finds that—

“(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

“(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or

“(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and

“(ii) the absence of adequate labeling could pose significant risks to pediatric patients.

“(2) WAIVERS.—

“(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

“(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

“(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

“(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

“(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

“(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

“(iii)(I) the drug or biological product—

“(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

“(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

“(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

“(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

“(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground

that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

“(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

“(3) RELATIONSHIP TO OTHER PEDIATRIC PROVISIONS.—

“(A) NO ASSESSMENT WITHOUT WRITTEN REQUEST.—No assessment may be required under paragraph (1) for a drug subject to an approved application under section 505 unless—

“(i) the Secretary has issued a written request for a related pediatric study under section 505A(c) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m);

“(ii)(I) if the request was made under section 505A(c)—

“(aa) the recipient of the written request does not agree to the request; or

“(bb) the Secretary does not receive a response as specified under section 505A(d)(4)(A); or

“(II) if the request was made under section 409I of the Public Health Service Act (42 U.S.C. 284m)—

“(aa) the recipient of the written request does not agree to the request; or

“(bb) the Secretary does not receive a response as specified under section 409I(c)(2) of that Act; and

“(iii)(I) the Secretary certifies under subparagraph (B) that there are insufficient funds under sections 409I and 499 of the Public Health Service Act (42 U.S.C. 284m, 290b) to conduct the study; or

“(II) the Secretary publishes in the Federal Register a certification that certifies that—

“(aa) no contract or grant has been awarded under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b); and

“(bb) not less than 270 days have passed since the date of a certification under subparagraph (B) that there are sufficient funds to conduct the study.

“(B) NO AGREEMENT TO REQUEST.—Not later than 60 days after determining that no holder will agree to the written request (including a determination that the Secretary has not received a response specified under section 505A(d) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m), the Secretary shall certify whether the Secretary has sufficient funds to conduct the study under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b), taking into account the prioritization under section 409I.

“(C) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B)(i) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary estimates that—

“(1) if approved, the drug or biological product would represent a significant improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

“(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

“(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit an assessment described in subsection (a)(2), or a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

“(1) the drug or biological product that is the subject of the assessment or request may

be considered misbranded and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but

“(2) the failure to submit the assessment or request shall not be the basis for a proceeding—

“(A) to withdraw approval for a drug under section 505(e); or

“(B) to revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

“(e) MEETINGS.—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—

“(1) information that the sponsor submits on plans and timelines for pediatric studies; or

“(2) any planned request by the sponsor for waiver or deferral of pediatric studies.

“(f) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

“(g) ORPHAN DRUGS.—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section [526.”.] 526.

“(h) INTEGRATION WITH OTHER PEDIATRIC STUDIES.—*The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(n).*”.

(b) CONFORMING AMENDMENTS.—

(1) Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) is amended in the second sentence—

(A) by striking “and (F)” and inserting “(F)”;

(B) by striking the period at the end and inserting “, and (G) any assessments required under section 505B.”.

(2) Section 505A(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(h)) is amended—

(A) in the subsection heading, by striking “REGULATIONS” and inserting “PEDIATRIC RESEARCH REQUIREMENTS”; and

(B) by striking “pursuant to regulations promulgated by the Secretary” and inserting “by a provision of law (including a regulation) other than this section”.

(3) Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended—

(A) by redesignating subparagraph (B) as subparagraph (C); and

(B) by inserting after subparagraph (A) the following:

“(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.”.

SEC. 3. TECHNICAL AND CONFORMING AMENDMENTS.

(a) ABBREVIATED NEW DRUG APPLICATION.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subparagraphs (A) and (B) of subsection (b)(2) and subparagraphs (A) and (B) of subsection (c)(2) by striking “505(j)(4)(B)” and inserting “505(j)(5)(B)”.

(b) PEDIATRIC ADVISORY COMMITTEE.—

(1) Section 505A(i)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(i)(2)) is amended by striking “Advisory Subcommittee of the Anti-Infective Drugs” each place it appears.

(2) Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note; Public Law 107-109) is amended—

(A) in the section heading, by striking “**PHARMACOLOGY**”;

(B) in subsection (a), by striking “(42 U.S.C. 217a),” and inserting “(42 U.S.C. 217a) or other appropriate authority,”;

(C) in subsection (b)—

(i) in paragraph (1), by striking “and in consultation with the Director of the National Institutes of Health”; and

(ii) in paragraph (2), by striking “and 505A” and inserting “505A, and 505B”; and

(D) by striking “pharmacology” each place it appears and inserting “therapeutics”.

(3) Section 15(a)(2)(A) of the Best Pharmaceuticals for Children Act (115 Stat. 1419) is amended by striking “Pharmacology”.

(4) Section 16(1)(C) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355a note; Public Law 107-109) is amended by striking “Advisory Subcommittee of the Anti-Infective Drugs”.

(5) Section 17(b)(1) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(b)(1)) is amended in the second sentence by striking “Advisory Subcommittee of the Anti-Infective Drugs”.

(6) Paragraphs (8), (9), and (11) of section 409(c) of the Public Health Service Act (42 U.S.C. 284m(c)) are amended by striking “Advisory Subcommittee of the Anti-Infective Drugs” each place it appears.

SEC. 4. EFFECTIVE DATE.

(a) **IN GENERAL.**—This Act and the amendments made by this Act take effect October 17, 2002.

(b) **NO LIMITATION OF AUTHORITY.**—Neither the lack of guidance or regulations to implement this Act or the amendments made by this Act nor the pendency of the process for issuing guidance or regulations shall limit the authority of the Secretary of Health and Human Services under, or defer any requirement under, this Act or those amendments.

Mr. DEWINE. Mr. President, I rise this evening in support of the passage of this bill, the pediatric rule. Passage of this bill will be a very important step in protecting the health of our children. This bill will help keep the pediatric rule in place to help ensure the drugs we give our children when they are sick are actually tested for use by our children. The tragic reality is there are medicines on the market today that are being used by and prescribed for our Nation's children that are oftentimes not being tested for their use. It has been that way for years and years.

For many years, doctors have had to take a chance when prescribing medicines for our kids. Doctors have literally had to tell parents to cut the pill in half or in quarters to be given to a child. The doctors have used the best information they have to literally guess how much medicine to give a child. That is all they could do with the medicines; they have had to guess.

Quite frankly, these medicines have been overprescribed, underprescribed, or maybe not prescribed at all when they should have been prescribed. For example, recently the drug Paxil, which is an antidepressant, has been prescribed without being tested in children at all. Many people have heard of this drug. Many people have heard of the beneficial effects for adults with anxiety and panic disorders. What peo-

ple did not know, what doctors did not know, was what we have recently found out. Recently the British Government has warned doctors to stop prescribing this drug for children, warning that the medicine increased the risk of suicide or suicidal thinking among children with depression. This action, in turn, spurred the FDA to conduct its own investigation into the safety of this drug for younger patients, resulting in a similar warning to physicians here in the United States: Don't prescribe this drug for children.

That is just one example. We have page after page of examples of drugs that have been prescribed to children in the past and once we then tested them, once the protocols were done, the testing was done, lo and behold, we found they were more effective for children than we thought. Sometimes they were not effective, sometimes the prescriptions, the amount, the dosage that had been used was too much, sometimes not enough.

The facts are these. As we all know, children are not just miniature adults. You can't just take the weight and just reduce the dosage. Kids react differently. That is why it is so important to have the testing done. Yet when Senator CHRIS DODD and I first started on this cause, 5 or 6 years ago, 80 percent of the drugs that came on the market had never been tested for children at all.

It has been over a year now since this Senate passed and the President signed into law the Best Pharmaceuticals for Children Act. The Best Act was a bill that followed the Better Pharmaceuticals for Children Act, which we passed a few years before that. That law, the Best Pharmaceuticals for Children Act, was part of the solution, just part of the solution to address the problem of getting medicines tested for use by children.

That law provides, as its predecessor bill did, a 6-month patent extension to pharmaceutical companies in exchange for the testing of medicines in children. That was a voluntary law and it has worked pretty well. For as long as the bill has been law—its predecessor was law—the Food and Drug Administration reported success in ensuring that more medicines are tested for use in children. With this economic incentive by this Best Pharmaceutical and Better Pharmaceutical bill in place, companies are seeing the value of studying their drugs in children and are applying for the patent extension, and children are benefiting.

But the Best Pharmaceuticals incentive cannot work alone. It was never intended to work alone to ensure that medicines for children are properly tested for their use. In order to ensure that no medicines needed to treat children, including vaccines or other biologics, would go untested, the FDA, in 1997, proposed what is known as the Pediatric Rule, a companion rule. The Pediatric Rule allowed the FDA to require that drugs deemed important for

children be tested for their safety, for their effectiveness, and that they be properly, then, labeled for children.

Unfortunately—and this is what brings us to the Senate floor tonight to consider this bill—the Pediatric Rule came under legal challenge and was, in fact, overturned in court in October 2002, last year, by a district court. That court ruled that the FDA lacked the statutory authority to require pediatric studies.

What the court said was it was incumbent upon Congress to fix it. That is why we are here tonight. This was a troubling step backward for children's health, considering that today 75 percent of the medicines on the market still, even with the Better Pharmaceutical bill and the Best Pharmaceutical bill, still 75 percent of the medicines on the market today are not tested and labeled for pediatric use.

Without the Pediatric Rule in place, without the necessary authority provided to the FDA, new medicines and biologics coming onto the market are not required to be tested for use in kids. Since that court decision on October 17, 2002, the FDA has indicated that over 300 medicines either have applications pending or incomplete studies pending, and that unless the Pediatric Rule stays in place these will all be lost. Many more, hundreds more will be lost in the future. Pediatricians will not know how to prescribe these drugs in the future or whether to prescribe them at all.

That is why Senator CLINTON, Senator DODD, and myself introduced the bill that we hope to pass tonight. It is a bill that would codify a significant piece of the Pediatric Rule to assure that it stays in place and ensures that children will remain on safe footing when it comes to the testing of the medications that they use.

Furthermore, we need to keep the Pediatric Rule in place right now because the Pediatric Rule and incentives work together to ensure that drugs are tested for use in children.

The Best Pharmaceuticals for Children Act, as I said already, was never intended to be a substitute for the rule but, rather, to reinforce and work with the rule. For example, the Pediatric Rule may be invoked in instances where pediatric information is essential but the patent exclusivity incentive is no longer available.

The Pediatric Rule also applies to biologics, whereas the Best Pharmaceutical bill does not. A significant portion of therapeutics used in children, including many cancer treatments or biological products—by that, of course, we mean products that include a live agent. Because the Best Pharmaceutical law does not apply to biologics, the Pediatric Rule is the only way to ensure proper and effective pediatric labeling.

Finally, the Best Pharmaceutical Act is voluntary. For any number of reasons, including insufficient sales, a manufacturer simply may choose to

not conduct the necessary testing to receive additional exclusivity under the "Best" law, and when that happens and the drug is not tested for kids, children are the losers. But just because a drug manufacturer chooses not to study the drug in children does not mean that the drug is not critical to the proper care of your children and my children or grandchildren. Without the Pediatric Rule that is in front of us today, there is no way to guarantee that a drug that is used in the pediatric population is tested for children's use.

With the establishment of the Pediatric Rule and the financial incentives of the Best Pharmaceutical law, which will go with this, there has been a dramatic increase in the number of studies that have been undertaken. Let me quote from the Government's Response to Plaintiff's Notice of Reauthorization of FDA Modernization Act. This is the document the Government filed to defend the lawsuit against the rule.

These two options—Best Pharmaceuticals for Children Act and the Pediatric Rule—have resulted in a number of drugs being labeled for use in pediatric applications. As of March 31, 2001, 94 applications containing complete or partial pediatric use and information have been submitted to the agency. Of these 94 applications, 45 are attributable to the statutory exclusivity provision. FDA attributes 48 of the 94 applications to the authority of the pediatric rule alone.

So you can see how the two must work together, how important the rule is. Our legislation is a step toward assuring this progress that we have made so far will not erode. Our bill, as amended, provides that the FDA may only impose the pediatric study requirement for already-marketed drugs when the pediatric exclusivity incentive provisions fail to yield necessary pediatric information. This means that for already-marketed drugs, drugs that the FDA has already approved and are already on the drugstore shelf, before FDA can require a company to study the drug for use in children, the incentive provisions of the Best Pharmaceuticals law have to be used first. So the drug manufacturer has to choose to use the incentive provisions first, before FDA can invoke the pediatric study requirement.

Our bill also preserves the waiver and deferral process so that drug companies can get waivers or deferrals for a range of legitimate reasons. Waivers are a simple concept.

Drugs, such as those used to treat Alzheimer's disease—those drugs that would not be used in children at all—obviously should not be tested for use in children. Those drug manufacturers would be allowed to waive the pediatric drug study requirement.

Deferrals are similar. For drug manufacturers who require additional time to complete the drug study or need to get additional information in the adult population before beginning to study the drug in children can, in consultation with the FDA, defer the pediatric drug studies until a later date.

Again, I am very pleased that my colleagues have agreed to pass our bill. It is a vital step toward ensuring that children are no longer a therapeutic afterthought.

Our bill puts children on a level playing field with adults for the first time.

Before I yield the floor, I would like to take this opportunity to thank the many people who have worked diligently to draft this bill and to help get it passed. I would like to thank Majority Leader FRIST and Senators CLINTON, DODD, GREGG, KENNEDY, and MURRAY for their leadership on this issue. Without their support, this bill would not be a reality.

I would also like to thank Abby Kral of my staff for her dedication and hard work on this issue—she spent an unbelievable amount of time on it—as well as Christina Ho from Senator CLINTON's Staff, Ben Berwick with Senator DODD, Vince Ventimiglia with Senator GREGG's Staff, and David Dorsey with Senator KENNEDY.

Finally, I would like to recognize two groups that provided my staff and the staff of the HELP Committee with invaluable comments and insights—the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation.

Thank you all for your efforts and commitment to protecting our children's health and safety.

Mr. KENNEDY. Mr. President, this important bill guarantees that drugs and biological products used for children are tested and labeled for children. It helps assure that the miracle cures of today can be administered to our children in safe and effective ways.

I commend Senators GREGG, CLINTON, DEWINE, and DODD for their effective and tireless leadership to see this important legislation through the Senate. And it is endorsed by the American Academy of Pediatrics, the Elizabeth Glaser Pediatric AIDS Foundation, the March of Dimes, and many other organizations dedicated to children's health.

Under this legislation, drug companies will be required to prove that their drugs and biological products are safe and effective for their intended use in children. For too long, drug companies have tested their products only in adults. For years, companies only rarely tested their drugs in children, unless the drug's use was for a juvenile disease. For other drugs, the label simply said that the product had not been shown to be safe and effective in children. To use such drugs on our children was a medical gamble.

Fortunately, that practice began to change 6 years ago. In 1997, Congress authorized 6 months of "pediatric exclusivity"—6 months of additional life of a drug patent if the company had studied the drug in children. The extra patent protection was a valuable economic incentive for drug companies to study their drugs on children, and it has been very successful in achieving that goal.

In 1998, FDA issued its Pediatric Rule, which allowed the agency to *require* a drug company to test and label certain drugs for children.

The patent exclusivity can be used once to study a drug. But the FDA rule can be used more than once, if needed, such as when the studies requested under exclusivity do not include studies in infants or newborns. In some cases, studies in older children are needed before studies can even be designed for younger children and newborn infants.

The rule can be used to require testing for biological products, which are not eligible for the extra patent exclusivity. The rule can also be used when a drug company decides not to seek extra patent exclusivity and does not study a drug in children.

Unfortunately, a Federal district court held that FDA does not have the statutory authority to issue the Pediatric Rule. Although the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation are appealing this decision, and we hope for their quick success, the Senate has now passed this legislation to correct the situation.

With this legislation, the essential protections of the rule will be codified in law: There will be a presumption that newly approved applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration for drugs and biological products will include assessments of safety and effectiveness for all relevant pediatric subpopulations. These assessments will support dosing and administration using a pediatric formulation for all pediatric subpopulations in which the product is safe and effective. This will be a huge step forward for children, and will put them on an equal footing with adults.

In addition, many products already on the market have meaningful therapeutic benefit to children or may be used for a substantial number of children. However, the absence of adequate labeling in these products poses significant risks to pediatric patients. This legislation will allow FDA to require such products to be studied in children for its approved indication. The bill requires that FDA must first provide an opportunity for these studies to be conducted under the provisions of the Best Pharmaceuticals for Children Act. However, if a product's manufacturer does not agree promptly to perform such studies voluntarily, and if funds are not sufficient so that the NIH or the Foundation for the NIH does not contract or issue a grant for conduct of the studies within a set period of time, FDA may invoke the authority in this legislation to require the studies. Although FDA never used this authority under its Pediatric Rule, we expect FDA to use it as necessary to ensure that drugs and biological products that are already approved are studied in children when other mechanisms to get them studied fail.

This legislation, with the managers' amendment, provides FDA with clear enforcement authority to bring a seizure or injunction action when a company fails to submit a required pediatric assessment. That failure alone will make the drug or biological product misbranded.

This legislation, with the managers' amendment, clarifies that assessments required under FDA's Pediatric Rule that have not yet been submitted to FDA, whether deferred until after approval or not, are assessments required under this legislation. The legislation therefore ensures that hundreds of assessments that FDA required under its rule will be completed for the benefit of the Nation's children.

Although this legislation is a giant step forward for children, I can't help but express my disappointment that its requirements are tied to the pediatric exclusivity provision that sunsets in 2007. Adults are guaranteed that new drugs will be reviewed for safety and effectiveness for them before they are approved by the FDA. Our Nation's children deserve no less. They should not have to come back in 4 years to plead for the right to safe and effective medicines.

Again, I commend my colleagues for reaching bipartisan agreement on this important initiative for children. I urge the House to act promptly to pass this bill so that children may quickly be protected by this legislation.

Mr. DEWINE. Mr. President, I ask unanimous consent that the committee amendment be agreed to, the Gregg amendment be agreed to, that the bill, as amended, be read a third time and passed, the motion to reconsider be laid upon the table, and that any statements and colloquies relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The committee amendment was agreed to.

The amendment (No. 1360) was agreed to, as follows:

AMENDMENT NO. 1360

On page 14, line 18, after "misbranded", insert "solely because of that failure".

On page 19, strike lines 5 and 6 and insert the following:

(a) IN GENERAL.—Subject to subsection (b), this Act and the amendments made by this Act take effect on the date of enactment of this Act.

(b) APPLICABILITY TO NEW DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall apply to an application described in paragraph (1) of that subsection submitted to the Secretary of Health and Human Services on or after April 1, 1999.

(2) WAIVERS AND DEFERRALS.—

(A) WAIVER OR DEFERRAL GRANTED.—If, with respect to an application submitted to the Secretary of Health and Human Services between April 1, 1999, and the date of enactment of this Act, a waiver or deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the waiver or deferral shall be a waiver or deferral under subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act, except that any date specified in such a defer-

ral shall be extended by the number of days that is equal to the number of days between October 17, 2002, and the date of enactment of this Act.

(B) WAIVER AND DEFERRAL NOT GRANTED.—If, with respect to an application submitted to the Secretary of Health and Human Services between April 1, 1999, and the date of enactment of this Act, neither a waiver nor deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the person that submitted the application shall be required to submit assessments under subsection (a)(2) of section 505B of the Federal Food, Drug, and Cosmetic Act on the date that is the later of—

(i) the date that is 1 year after the date of enactment of this Act; or

(ii) such date as the Secretary may specify under subsection (a)(3) of that section;

unless the Secretary grants a waiver under subsection (a)(4) of that section.

On page 19, line 7, strike "(b)" and insert "(c)".

PEDIATRICS RESEARCH AUTHORITY

Mr. GREGG. Mr. President, I rise to speak to a managers' amendment to S. 650, the Pediatric Research Equity Act. This amendment makes improvements to the legislation as reported out of the Committee on Health, Education, Labor and Pensions in June. Because these improvements were made after the committee report was filed, this statement is intended to serve as the committee's views on the amended legislation. This statement was shared with the other committee members and has their concurrence.

Mr. KENNEDY. Mr. President, the Democratic sponsors of the bill and I concur with this statement.

Mr. GREGG. Mr. President, the purpose of this legislation is to provide FDA with statutory authority to require pediatric studies in specified circumstances. In October 2002, a Federal district court held that existing law did not provide FDA the authority to issue a regulation requiring pediatric studies for drugs marketed to adults but important to children. Although this decision is being appealed, this legislation will provide the agency with definitive statutory authority to require pediatric studies of new and already marketed drugs and biologics in the circumstances specified in the legislation and to enforce any violations of those requirements in Federal court. This has always been the intent of S. 650. After the legislation was marked up in committee, the managers of the bill agreed to amend the language in section 505B(d) to make this intent even clearer.

The enforcement mechanism in section 505B(d) provides that if a person fails to submit an assessment described in subsection (a)(2) or a request for approval of a pediatric formulation described in subsection (a) or (b) under the new law, "the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of such failure." This language confers on the Secretary authority to bring a misbranding action where a violation has occurred.

The committee has used the language "may be considered" (misbranded)

rather than the traditional "shall be deemed to be" (misbranded) that is used in other provisions of the Federal Food, Drug and Cosmetic Act in order to emphasize that the Secretary may exercise traditional enforcement discretion in deciding whether to bring such an action. The Committee recognizes that the Secretary retains that discretion under other provisions of current law that use the "shall" formulation. Nevertheless, the Committee intends for this authority to be interpreted by the courts and to be implemented by FDA in a manner consistent with the agency's enforcement authorities in current law that use the "shall" formulation.

As is true with other provisions of current law, once the Secretary decides to initiate an enforcement action under section 505B(d), no formal finding or other proceeding is required. Moreover, it is not necessary for the Secretary to identify any other misbranding authority in the act. The new authority conferred by section 505B(d) is sufficient. For example, the failure of a sponsor to submit pediatric studies in accordance with the requirements of the legislation alone would be a sufficient basis to prosecute an action in federal district court.

The managers of the bill have agreed to the extraordinary retroactive application of the provisions of the new research authority in order to avoid even greater potential harm to children through the loss of research and agency resources should assessments, waivers, and deferrals under the Pediatric Rule be considered invalid following the recent district court decision invalidating the rule. This application should not be considered approval of the agency's interpretation of its authority nor disagreement of the court's ruling. In the extraordinary situation at hand, the managers' amendment modifies the effective date provision of the legislation to ensure a seamless transition of the pediatric study requirement from the Pediatric rule to this legislation. The intent is that waivers and deferrals of the study requirement previously granted under the rule be deemed to be in effect under the legislation. A sponsor that received a deferral under the rule would have the original deferral date extended by the number of days between October 17, 2002, and the date of enactment of this legislation.

A sponsor that submitted an application in the time period between April 1, 1999, and the date of enactment of this legislation that was not granted a waiver or deferral under the rule would be required to submit pediatric assessments unless granted a waiver by FDA. However, no submission by a sponsor would be due until 12 months after the date of enactment of this legislation or until a date specified by FDA under section 505B(a)(3), whichever is later.

Mr. KENNEDY. Mr. President, Although I and the Democratic sponsors

of the bill disagree with the chairman's view that the agency lacked the authority to promulgate the Pediatric Rule and his view that the Federal district court ruling invalidating the rule was correct, we do agree with the chairman's statements regarding the need to apply the requirements of this legislation retroactively to ensure that no pediatric studies are lost in the transition from the rule to this legislation.

Mr. GREGG. Mr. President, S. 650 provides FDA the statutory authority to require that new and already marketed drugs and biological products be studied in children in specified circumstances. This authority is intended to work in a complementary fashion with pediatric exclusivity. With regard to already marketed products, S. 650 provides that FDA require pediatric testing only after pediatric exclusivity and the National Institutes of Health grant and contract provisions contained in sections 409I and 499 of the Public Health service Act have failed to produce the necessary studies. However, nothing in S. 650 requires FDA to wait until the voluntary mechanisms have failed or been exhausted before invoking the pediatric studies requirement for new drug applications under section 505 of the Federal Food, Drug and Cosmetic Act or biological license applications under section 351 of the Public Health service Act. On the contrary, S. 650 creates the presumption that new drugs and biologics will be studied before approval unless a waiver or deferral is granted.

Mr. KENNEDY. Mr. President, I agree with the Senator. Does he agree as well, that, in accordance with the plain language of the legislation, FDA shall grant a waiver of the requirement to submit pediatric assessments only if the applicant certifies and the Secretary finds that the conditions specified in 505B(a)(4) and 505B(b)(2) exist? By using the word "including" before listing the circumstances under which FDA shall grant a full or partial waiver in the committee report for S. 650, the committee does not intend that any conditions or circumstances other than those specifically stated in 505B(a)(4) and 505B(b)(2) serve as the basis for FDA granting a full or partial waiver of the requirements of the legislation.

Mr. GREGG. Mr. President, I do, and I thank the Senator for his work on this bill and the report.

The bill (S. 650), as amended, was read the third time and passed as follows:

S. 650

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pediatric Research Equity Act of 2003".

SEC. 2. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505A the following:

"SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

"(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—A person that submits an application (or supplement to an application)—

"(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

"(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration;

shall submit with the application the assessments described in paragraph (2).

"(2) ASSESSMENTS.—

"(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

"(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

"(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

"(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

"(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

"(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from 1 age group can be extrapolated to another age group.

"(3) DEFERRAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

"(A) the Secretary finds that—

"(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

"(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

"(iii) there is another appropriate reason for deferral; and

"(B) the applicant submits to the Secretary—

"(i) certification of the grounds for deferring the assessments;

"(ii) a description of the planned or ongoing studies; and

"(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.

"(4) WAIVERS.—

"(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or the patients are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be

ineffective or unsafe in all pediatric age groups; or

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

"(II) is not likely to be used in a substantial number of pediatric patients.

"(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

"(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

"(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

"(b) MARKETING DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—After providing notice in the form of a letter and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) if the Secretary finds that—

"(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

"(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or

"(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and

"(ii) the absence of adequate labeling could pose significant risks to pediatric patients.

"(2) WAIVERS.—

"(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

"(ii) there is evidence strongly suggesting that the drug or biological product would be

ineffective or unsafe in all pediatric age groups.

"(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii) (I) the drug or biological product—

"(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

"(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

"(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

"(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

"(3) RELATIONSHIP TO OTHER PEDIATRIC PROVISIONS.—

"(A) NO ASSESSMENT WITHOUT WRITTEN REQUEST.—No assessment may be required under paragraph (1) for a drug subject to an approved application under section 505 unless—

"(i) the Secretary has issued a written request for a related pediatric study under section 505A(c) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m);

"(ii) (I) if the request was made under section 505A(c)—

"(aa) the recipient of the written request does not agree to the request; or

"(bb) the Secretary does not receive a response as specified under section 505A(d)(4)(A); or

"(II) if the request was made under section 409I of the Public Health Service Act (42 U.S.C. 284m)—

"(aa) the recipient of the written request does not agree to the request; or

"(bb) the Secretary does not receive a response as specified under section 409I(c)(2) of that Act; and

"(iii) (I) the Secretary certifies under subparagraph (B) that there are insufficient funds under sections 409I and 499 of the Public Health Service Act (42 U.S.C. 284m, 290b) to conduct the study; or

"(II) the Secretary publishes in the Federal Register a certification that certifies that—

"(aa) no contract or grant has been awarded under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b); and

"(bb) not less than 270 days have passed since the date of a certification under subparagraph (B) that there are sufficient funds to conduct the study.

"(B) NO AGREEMENT TO REQUEST.—Not later than 60 days after determining that no holder will agree to the written request (including a determination that the Secretary has not received a response specified under sec-

tion 505A(d) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m), the Secretary shall certify whether the Secretary has sufficient funds to conduct the study under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b), taking into account the prioritization under section 409I.

"(C) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B)(i) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary estimates that—

"(1) if approved, the drug or biological product would represent a significant improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

"(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

"(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit an assessment described in subsection (a)(2), or a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

"(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but

"(2) the failure to submit the assessment or request shall not be the basis for a proceeding—

"(A) to withdraw approval for a drug under section 505(e); or

"(B) to revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

"(e) MEETINGS.—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—

"(1) information that the sponsor submits on plans and timelines for pediatric studies; or

"(2) any planned request by the sponsor for waiver or deferral of pediatric studies.

"(f) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

"(g) ORPHAN DRUGS.—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.

"(h) INTEGRATION WITH OTHER PEDIATRIC STUDIES.—The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(n)."

(b) CONFORMING AMENDMENTS.—

(1) Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) is amended in the second sentence—

(A) by striking "and (F)" and inserting "(F)"; and

(B) by striking the period at the end and inserting ", and (G) any assessments required under section 505B."

(2) Section 505A(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(h)) is amended—

(A) in the subsection heading, by striking "REGULATIONS" and inserting "PEDIATRIC RESEARCH REQUIREMENTS"; and

(B) by striking "pursuant to regulations promulgated by the Secretary" and inserting "by a provision of law (including a regulation) other than this section".

(3) Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended—

(A) by redesignating subparagraph (B) as subparagraph (C); and

(B) by inserting after subparagraph (A) the following:

"(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act."

SEC. 3. TECHNICAL AND CONFORMING AMENDMENTS.

(a) ABBREVIATED NEW DRUG APPLICATION.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subparagraphs (A) and (B) of subsection (b)(2) and subparagraphs (A) and (B) of subsection (c)(2) by striking "505(j)(4)(B)" and inserting "505(j)(5)(B)".

(b) PEDIATRIC ADVISORY COMMITTEE.—

(1) Section 505A(i)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(i)(2)) is amended by striking "Advisory Subcommittee of the Anti-Infective Drugs" each place it appears.

(2) Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note; Public Law 107-109) is amended—

(A) in the section heading, by striking "PHARMACOLOGY";

(B) in subsection (a), by striking "(42 U.S.C. 217a)," and inserting "(42 U.S.C. 217a) or other appropriate authority,";

(C) in subsection (b)—

(i) in paragraph (1), by striking "and in consultation with the Director of the National Institutes of Health"; and

(ii) in paragraph (2), by striking "and 505A" and inserting "505A, and 505B"; and

(D) by striking "pharmacology" each place it appears and inserting "therapeutics".

(3) Section 15(a)(2)(A) of the Best Pharmaceuticals for Children Act (115 Stat. 1419) is amended by striking "Pharmacology".

(4) Section 16(1)(C) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355a note; Public Law 107-109) is amended by striking "Advisory Subcommittee of the Anti-Infective Drugs".

(5) Section 17(b)(1) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(b)(1)) is amended in the second sentence by striking "Advisory Subcommittee of the Anti-Infective Drugs".

(6) Paragraphs (8), (9), and (11) of section 409I(c) of the Public Health Service Act (42 U.S.C. 284m(c)) are amended by striking "Advisory Subcommittee of the Anti-Infective Drugs" each place it appears.

SEC. 4. EFFECTIVE DATE.

(a) IN GENERAL.—Subject to subsection (b), this Act and the amendments made by this Act take effect on the date of enactment of this Act.

(b) APPLICABILITY TO NEW DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall apply to an application described in paragraph (1) of that subsection submitted to the Secretary of Health and Human Services on or after April 1, 1999.

(2) WAIVERS AND DEFERRALS.—

(A) WAIVER OR DEFERRAL GRANTED.—If, with respect to an application submitted to the Secretary of Health and Human Services

between April 1, 1999, and the date of enactment of this Act, a waiver or deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the waiver or deferral shall be a waiver or deferral under subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act, except that any date specified in such a deferral shall be extended by the number of days that is equal to the number of days between October 17, 2002, and the date of enactment of this Act.

(B) **WAIVER AND DEFERRAL NOT GRANTED.**—If, with respect to an application submitted to the Secretary of Health and Human Services between April 1, 1999, and the date of enactment of this Act, neither a waiver nor deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the person that submitted the application shall be required to submit assessments under subsection (a)(2) of section 505B of the Federal Food, Drug, and Cosmetic Act on the date that is the later of—

(i) the date that is 1 year after the date of enactment of this Act; or

(ii) such date as the Secretary may specify under subsection (a)(3) of that section; unless the Secretary grants a waiver under subsection (a)(4) of that section.

(C) **NO LIMITATION OF AUTHORITY.**—Neither the lack of guidance or regulations to implement this Act or the amendments made by this Act nor the pendency of the process for issuing guidance or regulations shall limit the authority of the Secretary of Health and Human Services under, or defer any requirement under, this Act or those amendments.

Mr. DODD. Mr. President, I rise today to applaud my colleagues for passing the Pediatric Research Equity Act of 2003, and to thank all of those who have worked so hard on this issue. This legislation represents a truly bipartisan compromise, and I deeply appreciate the commitment to this issue shown by Senators DEWINE, CLINTON, GREGG, and KENNEDY. I also acknowledge the invaluable role played by the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation.

Quite simply, this legislation will make our children safer. It will ensure that they have access to prescription drugs that have been properly evaluated for their use. It will remove the guesswork often done by pediatricians about what drugs are appropriate for a child, and in what dosages. And it will accomplish all of this by codifying into statutory language a tool that has already been shown to be effective: the Pediatric Rule.

The Pediatric Rule went into effect in April of 1999 and was intended to work in conjunction with a voluntary incentives program that Congress passed in 1997 and was reauthorized last year. Both the incentives program and the rule were put into place to address an unmet need that had potentially serious consequences to the health of children.

Children are not just small versions of adults when it comes to drugs. Some drugs that are completely safe for adults may be very harmful to children. In addition, some needed drugs are not available in a formulation that a child can take, such as a liquid or chewable tablet. Finally, the appro-

priate dosage for a child cannot be determined simply by extrapolating from adults. Yet, until the rule and the incentives program were enacted, this is exactly what pediatricians were forced to do. Roughly 75 percent of all prescription drugs on the market today have never been properly tested for safe use by children.

As a result, children have suffered needlessly. For example, new tests on the epilepsy drug Neurontin have shown that higher dosages than expected are needed for children under 5. For years, pediatricians simply believed that Neurontin was a drug that was ineffective for children.

In 1997, Congress enacted legislation, introduced by Senator DEWINE and myself, to provide drug companies with an economic incentive to test their products to ensure their safety in children. This was followed by enactment of the Pediatric Rule in 1999, which worked with the incentive by giving the Food and Drug Administration (FDA) the authority to require that drugs and biologics important to children be tested and formulated for their use.

Working as complements to each other, the rule and the incentive provided tremendous results. Between April 1999 and March 2002, research was completed on the safety and effectiveness in children of roughly 100 drugs. These medicines were for the treatment of, among other things, HIV/AIDS, diabetes, asthma pain and arthritis. In addition, studies of hundreds more drugs are in the pipeline.

But continued success of this magnitude is dependent on the existence of both the rule and the incentive program. FDA has stated that approximately half of the completed studies were due to the authority provided by the Pediatric Rule.

Unfortunately, in October of last year, the U.S. District Court for the District of Columbia ruled that FDA does not have the authority to enforce the rule. This decision represented a step backwards for children's health. We can hardly afford to do without the rule when we still do not have necessary information for kids for a majority of the medicines on the market.

The legislation that we passed today will give the FDA clear authority to require that drugs be tested and formulated for children. Companies should continue to have access to voluntary incentives, but the rule must be in place to ensure that as many products as possible are studied for use in children.

For example, the rule captures a class of products, specifically biologics, for which market exclusivity incentives do not apply. There are a number of biologic products used to treat cancer in children for which information about their specific use—safety and efficacy—in kids would be vital. Only the rule would apply here.

The rule can also be applied as needed during the life of a drug as more information is required. For example, if a

new use of a drug is discovered and safety or dosing information for that new use is needed. Exclusivity can only be applied once, even if an important new use for a product is found. Also, because the incentives are voluntary, for any number of reasons a manufacturer may choose not to conduct the necessary testing. Without the rule there is no way to guarantee that a drug that may be critically important to children's health is tested.

I would be remiss if I did not mention one provision in this legislation with which I disagree. As a result of this provision, the authority that we clearly provide to FDA with this bill will sunset in 2007. While I believe that FDA has the authority to enforce the rule even without this legislation, that has clearly been called into question given the District Court ruling. Therefore, it is imperative that we unequivocally and permanently provide the FDA with statutory authority to require pediatric testing. Unfortunately, as it now stands that critical authority will expire in 2007 unless reauthorized.

It is my view that such a reauthorization should not be necessary. We take it for granted that studies will be done to assure that the drugs that adults use are safe and effective. Why should the assumption be any different for children? FDA should always have the authority to make sure that the drugs that kids use have been tested for their use. This is not something that Congress should have to reauthorize every 5 years. Kids should not have to come back to Congress every 5 years to fight for the basic right to safe drugs.

Despite my concern with the sunset provision, I strongly support this bill. The voluntary program has been a huge success, but its limitations can be addressed by passage of this legislation. Simply put, taking any tool off the table that promotes pediatric testing is at odds with our overarching goal of ensuring that medicines are safe and available for our children. That is why we must protect the rule and ensure that our efforts for kids will not be diminished. The Pediatric Research Equity Act of 2003 will do exactly that.

I sincerely hope that the House will pass this bill as soon as possible, preferably without any changes so that we can send it to the President to be signed into law without delay.

Mrs. CLINTON. Mr. President, I rise to mark the passage on the Senate floor of a bill, S. 650, that will assure the safety and efficacy of medicines for children, and address a problem that pediatricians, parents, and children's advocates have worked on for decades. A great deal of work went into this bill. So many hardworking, dedicated Senators made the effort on a bipartisan basis to come together around this important issue. In particular I want to thank Senators DEWINE, DODD, GREGG, and KENNEDY. Senators DEWINE and DODD and I now have worked on pediatric research for many years, and we

will continue to be around to work on behalf of children, who, without dedicated advocates like Senators DEWINE and DODD, would not have a political voice.

Last year this bill was passed out of committee but held up on the floor toward the end of session. Unfortunately, that meant no backstop was in place to assure the continuation of a minimum baseline protection for children when last October, a District Court judge struck down the 1998 FDA Pediatric Rule, based on his view that Congress did not intend to charge FDA with making sure our children are protected. Today, we pass legislation to clarify that FDA authority to assure safe, effective medicines for children is exactly what we intend.

This bill was the product of compromise. We all worked hard and made concessions on all sides to craft the language the Senate was able to pass today. Some of us would have preferred a strong, permanent assurance for children, and not a sunset of these crucial protections in 2007. Indeed, because the purpose of this legislation was to address the uncertainty caused by the court-triggered lapse of pediatric studies, not codify such a lapse into statute, I cannot support the sunset provision.

But others may have wished to change other aspects of the bill. So we were able to give on each side for the sake of moving forward on a central accomplishment providing FDA with undisputed, unencumbered authority to require and enforce studies of whether medicines important for children are also safe and effective for children. Our managers' amendment and the colloquy we submitted today reinforce that as the goal we all share here today in passing this language.

I want to take a moment to bring special attention to the amount of work and cooperation that the chair and ranking member of Senate Health Education, Labor, and Pensions Committee have dedicated to this bill, both last Congress and this Congress. Senator GREGG and Senator KENNEDY, and both their staffs, Vince Ventimiglia, and David Dorsey have lent their expertise and their time to this issue. Senator DEWINE's staff, Abby Kral, and Senator DODD's staff, Ben Berwick this year, Debra Barrett last year, have been more dedicated than anyone on this issue.

I particularly want to acknowledge the outside experts who have devoted so much time to advocating on behalf of children and making this proposal a reality. The American Academy of Pediatricians, Elaine Vining here in DC and all the pediatricians across the country, have been championing this issue for so long. Also, Mark Isaac and Jeanne Ireland at the Elizabeth Glaser Pediatric AIDS Foundation have been tireless in their efforts. The children's hospitals, and so many others cannot be thanked enough. We would not be here today without their passionate ad-

vocacy. I also appreciate working with Phrma to get to this point and hope to continue to work with them in order to move this bill quickly into law.

NATIVE AMERICAN ALCOHOL AND SUBSTANCE ABUSE PROGRAM CONSOLIDATION ACT OF 2003

Mr. DEWINE. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of calendar No. 143, S. 285.

The PRESIDING OFFICER. The clerk will report the bill by title.

The assistant legislative clerk read as follows:

A bill (S. 285) to authorize the integration and consolidation of alcohol and substance abuse programs and services provided by Indian tribal governments, and for other purposes.

There being no objection, the Senate proceeded to consider the bill which had been reported from the Committee on Indian Affairs, with an amendment to strike all after the enacting clause and inserting in lieu thereof the following:

[Strike the part shown in black brackets and insert the part shown in italic.]

S. 285

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

[This Act may be cited as the "Native American Alcohol and Substance Abuse Program Consolidation Act of 2003".]

SEC. 2. PURPOSES.

[The purposes of this Act are—

[(1) to enable Indian tribes to consolidate and integrate alcohol and other substance abuse prevention, diagnosis, and treatment programs, and mental health and related programs, to provide unified and more effective and efficient services to Indians afflicted with mental health, alcohol, or other substance abuse problems;

[(2) to recognize that Indian tribes can best determine the goals and methods for establishing and implementing prevention, diagnosis, and treatment programs for their communities, consistent with the policy of self-determination;

[(3) to encourage and facilitate the implementation of an automated clinical information system to complement the Indian health care delivery system;

[(4) to authorize the use of Federal funds to purchase, lease, license, or provide training for technology for an automated clinical information system that incorporates clinical, financial, and reporting capabilities for Indian behavioral health care programs;

[(5) to encourage quality assurance policies and procedures, and empower Indian tribes through training and use of technology, to significantly enhance the delivery of, and treatment results from, Indian behavioral health care programs;

[(6) to assist Indian tribes in maximizing use of public, tribal, human, and financial resources in developing effective, understandable, and meaningful practices under Indian behavioral health care programs; and

[(7) to encourage and facilitate timely and effective analysis and evaluation of Indian behavioral health care programs.

SEC. 3. DEFINITIONS.

[In this Act:

[(1) AUTOMATED CLINICAL INFORMATION SYSTEM.—The term "automated clinical infor-

mation system" means an automated computer software system that can be used to manage clinical, financial, and reporting information for Indian behavioral health care programs.

[(2) FEDERAL AGENCY.—The term "Federal agency" has the meaning given the term "agency" in section 551 of title 5, United States Code.

[(3) INDIAN.—The term "Indian" has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

[(4) INDIAN BEHAVIORAL HEALTH CARE PROGRAM.—The term "Indian behavioral health care program" means a federally funded program, for the benefit of Indians, to prevent, diagnose, or treat, or enhance the ability to prevent, diagnose, or treat—

[(A) mental health problems; or

[(B) alcohol or other substance abuse problems.

[(5) INDIAN TRIBE.—

[(A) IN GENERAL.—The term "Indian tribe" has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

[(B) INCLUSIONS.—The term "Indian tribe", in a case in which an intertribal consortium, tribal organization, or Indian health center is authorized to carry out 1 or more programs, services, functions, or activities of an Indian tribe under this Act, includes the intertribal consortium, tribal organization, or Indian health center.

[(6) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

[(7) SUBSTANCE ABUSE.—The term "substance abuse" includes—

[(A) the illegal use or abuse of a drug or an inhalant; and

[(B) the abuse of tobacco or a related product.

SEC. 4. PLANS.

[The Secretary, in cooperation with the Secretary of Labor, the Secretary of the Interior, the Secretary of Education, the Secretary of Housing and Urban Development, the Attorney General, and the Secretary of Transportation, as appropriate, shall, on receipt of a plan acceptable to the Secretary that is submitted by an Indian tribe, authorize the Indian tribe to carry out a demonstration project to coordinate, in accordance with the plan, the Indian behavioral health care programs of the Indian tribe in a manner that integrates the program services into a single, coordinated, comprehensive program that uses, to the extent necessary, an automated clinical information system to better manage administrative and clinical services, costs, and reporting requirements through the consolidation and integration of administrative and clinical functions.

SEC. 5. PROGRAMS AFFECTED.

[Programs that may be integrated in a demonstration project described in section 4 are—

[(1) an Indian behavioral health care program under which an Indian tribe is eligible for the receipt of funds under a statutory or administrative formula;

[(2) an Indian behavioral health care program under which an Indian tribe is eligible for receipt of funds through competitive or other grants, if—

[(A)(i) the Indian tribe provides notice to the appropriate agency regarding the intentions of the Indian tribe to include the Indian behavioral health care program in the plan that the Indian tribe submits to the Secretary; and

[(ii) the agency consents to the inclusion of the grant in the plan; or

[(B)(i) the Indian tribe elects to include the Indian behavioral health care program in the plan; and